

[ORAL ARGUMENT NOT YET SCHEDULED]
IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TAKEDA PHARMACEUTICALS U.S.A.,
INC., and

ELLIOTT ASSOCIATES, L.P., ET AL.,

Appellants,

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,

Amicus Curiae for Appellants,

v.

SYLVIA MATHEWS BURWELL, in her
official capacity as SECRETARY, U.S.
DEPARTMENT OF HEALTH AND
HUMAN SERVICES, ET AL.,

Appellees,

HIKMA PHARMACEUTICALS PLC, ET
AL.,

Intervenors for Appellees.

No. 15-5021 &
No. 15-5022

**UNOPPOSED MOTION FOR A 30-DAY EXTENSION OF TIME
IN WHICH TO FILE THE GOVERNMENT'S RESPONSE BRIEF**

For the reasons set forth below, the government respectfully requests a 30-day extension, to and including October 16, 2015, of the time for filing the government's response brief in these consolidated appeals. The parties jointly request that, if the

Court grants the requested extension, it also extend the deadline for filing the joint intervenor brief to October 16, 2015, and extend the deadline for filing the reply briefs to October 30, 2015, as outlined below. This is our first request for an extension. This motion is unopposed.

1. These cases are appeals from the United States District Court for the District of Columbia. Appellants Takeda Pharmaceuticals U.S.A., Inc., Elliott Associates, L.P., Elliott International, L.P., and Knollwood Investments, L.P., seek review of the district court's orders granting the government's motions for summary judgment and upholding FDA's approval of a new drug application submitted by intervenors Hikma Pharmaceuticals PLC and West-Ward Pharmaceuticals Corp. See *Elliott Associates, L.P. v. Burwell*, No. 14-cv-1850 (Jan. 9, 2015) (Hon. Kentaji Brown Jackson); *Takeda Pharmaceuticals U.S.A., Inc. v. Burwell*, No. 14-cv-1668 (Jan. 15, 2015) (Hon. Kentaji Brown Jackson).

2. Appellant Takeda Pharmaceuticals U.S.A., Inc., filed a notice of appeal in this Court on January 26, 2015 (No. 15-5021). Appellants Elliott Associates, L.P., Elliott International, L.P., and Knollwood Investments, L.P., filed a notice of appeal in this Court on January 26, 2015 (No. 15-5022). This Court consolidated these cases on its own motion. See Order, No. 15-5021 (lead case), docket entry #2 (Jan. 25, 2015).

3. Appellants filed their opening briefs in this Court on August 17, 2015. The government's response brief is presently due on September 16, 2015. We have not previously sought an extension.

4. The requested 30-day extension is necessary in light of other pressing appellate matters with proximate deadlines for which government counsel are responsible.

The attorney with principal responsibility for preparing the government's brief in this appeal is Sonia K. McNeil. Ms. McNeil is also principal counsel for the government in *Beck v. McDonald*, No. 15-1395 (4th Cir.), and *Watson v. McDonald*, No. 15-1715 (4th Cir.). The government's brief in these consolidated appeals is presently due to the Fourth Circuit on September 11, 2015, only three business days before the government's brief is presently due in this case.

Ms. McNeil is also principal counsel for the government in *Mitchael v. Colvin*, No. 14-3220 (8th Cir.). Ms. McNeil is scheduled to present oral argument in that case on behalf of the government before the Eighth Circuit on September 21, 2015, only three business days after the government's brief is presently due in this case.

5. For the foregoing reasons, the requested 30-day extension is necessary to permit government counsel adequate time to consult with our clients in this case and to prepare and file an appropriate brief.

6. We have consulted with counsel for appellants and intervenors. Counsel for Takeda and the Elliott Appellants do not oppose the requested relief, provided that

any extension does not delay the scheduling of oral argument in this case, and the case is set for oral argument on the first practicable date after the briefing is completed.

Counsel for intervenors have authorized us to state that this motion is unopposed.

7. The parties additionally request that, if the Court grants the requested 30-day extension for the government's brief, it also extend the deadline for filing the joint intervenor brief to October 16, 2015, and extend the deadline for filing the reply briefs to October 30, 2015. This results in the following modified briefing schedule:

	Current schedule	Proposed schedule
Government brief	September 16	October 16
Intervenor brief	September 16	October 16
Reply briefs	September 30	October 30

All parties consent to modification of the briefing schedule as proposed above.

CONCLUSION

For the foregoing reasons, we respectfully request that the Court grant a 30-day extension, to and including October 16, 2015, of the time for filing the government's brief in this appeal. The parties additionally jointly request that, if the Court grants the requested 30-day extension for the government's brief, it also extend the deadline for filing the joint intervenor brief to October 16, 2015, and extend the deadline for filing the reply briefs to October 30, 2015.

Respectfully submitted,

SCOTT R. McINTOSH

/s/ Sonia K. McNeil

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Counsel for Appellees

AUGUST 2015

CERTIFICATE OF SERVICE

I hereby certify that on August 31, 2015, I electronically filed the foregoing motion with the Clerk of Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system. I further certify that all participants in this case are registered CM/ECF users and will be served through the CM/ECF system.

/s/ Sonia K. McNeil

Sonia K. McNeil